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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,026	07/22/1999	ELAINE M. TOBIN	36316.00007	2252

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EXAMINER	
KRUSE, DAVID H	
ART UNIT	PAPER NUMBER
1638	23

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/359,026	TOBIN ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)[·] Responsive to communication(s) filed on *13 February 2002 and 08 April 2002* .

2a)[ ] This action is **FINAL**. 2b)[×] This action is non-final.

3)[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)[·] Claim(s) *1,2 and 4-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)[·] Claim(s) *1 and 2* is/are allowed.

6)[·] Claim(s) *4-6,8 and 9* is/are rejected.

7)[·] Claim(s) *7* is/are objected to.

8)[ ] Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)[ ] The specification is objected to by the Examiner.

10)[ ] The drawing(s) filed on _____ is/are: a)[ ] accepted or b)[ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)[ ] The proposed drawing correction filed on _____ is: a)[ ] approved b)[ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)[ ] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)[ ] All b)[ ] Some * c)[ ] None of:

1.[ ] Certified copies of the priority documents have been received.

2.[ ] Certified copies of the priority documents have been received in Application No. _____ .

3.[ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)[·] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15)[ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [×] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) [ ] Interview Summary (PTO-413) Paper No(s). _____ .
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 13 February 2002 and 8 April 2002.

2. The application is now in compliance with the Sequence Rules.

3. Those Rejections not specifically addressed in this Office Action are withdrawn in view of Applicant's amendments and/or arguments.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

5. The drawings in this application remain objected to by the Draftsperson as informal. See the attached PTO-948 form attached to Paper No. 15, mailed on 26 September 2001. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

Claim Objections

6. Claims 1 and 4-8 are objected to because the phrase "SEQ. I.D. No." introduces more than one period into the sentence and said phrase should read -- SEQ ID NO: --.

7. Claim 7 objected to because of the following informalities: At line 2 the phrase "transforming the plant with the nucleic acid sequence of" is unclear because "nucleic acid sequence" is information and not a composition of matter. Amending the claim to

read -- transforming the plant with a nucleic acid having the sequence of -- would obviate this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 4, 8 and 9 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant rejection is made in view of Applicant's amendments to the claims.

At claim 4, the phrase "A host cell transformed with a heterologous polypeptide" is indefinite because it is unclear how one of skill in the art transforms a host cell with a polypeptide, hence it is unclear what the metes and bounds of the claim are. The phrase -- A host cell transformed with a nucleic acid that encodes a heterologous polypeptide -- is suggested.

Claim 8 is indefinite because it is unclear what the plant of the method is transformed with to alter expression of a polypeptide having the amino acid sequence of SEQ ID NO: 2, hence it is unclear what the metes and bounds of the claimed invention are.

At claim 8, line 3, the phrase "having either the amino acid sequence of SEQ. I.D. NO: 2" is indefinite, hence it is unclear what the metes and bounds of the claim are.

At claim 9, line 2, the phrase "changing activity of protein kinase" is indefinite because it is unclear what the metes and bounds of "changing activity" are. In addition, the step does not appear to constitute an act of man, but rather a natural biological phenomenon, and hence there are no positive method steps in the claimed method.

9. Claims 4, 6, 8 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a host cell transformed with and a transgenic plant overexpressing a polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence shown in SEQ. I.D. No. 2. Applicant also claims a method of altering circadian rhythms and flowering in a plant comprising altering expression of a polypeptide or changing activity of protein kinase CK2 within the plant, or transforming the plant with an unidentified nucleic acid.

Applicant describes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that is a β-subunit of an *Arabidopsis thaliana* CK2 protein kinase (CKB3) (see pages 11-12 of the specification). In addition, Applicant teaches altering the flowering time in a plant by overexpressing said CKB3 (see pages 19-24 of the specification).

Applicant does not describe the genus of polypeptides that are 80% identical to SEQ I.D. No. 2 or nucleic acids that encode such polypeptides. In addition, Applicant does not teach the genus of starting materials that one of skill in the art could use in a method of altering circadian rhythms and flowering in a plant by changing activity of protein kinase CK2 within the plant (see Claims 8 and 9).

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. The instant specification fails to provide an adequate written description of the genus required to practice the claimed invention.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. Because Applicant has only described a single species within a genus, Applicant has not adequately provided sufficient identifying characteristics for written description purposes.

10. Claim 8 remains rejected and claims 4-6 and 9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a host cell and a transgenic plant transformed with a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2 and a method of modifying flowering time in a plant comprising transforming a plant with a nucleic acid encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2, the specification is not enabling for a host cell transformed with a heterologous polypeptide, any transgenic plant overexpressing a nucleic acid complementary to SEQ ID NO: 1, a method comprising transforming a plant with any nucleic acid to alter expression of a polypeptide having the amino acid sequence of SEQ ID NO: 2 or a method comprising changing activity of protein kinase CK2 within a plant by any means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection has been modified from that of the previous Office action mailed 26 September 2001.

This rejection has been modified from the previous rejection to further limit the scope of enablement to a method of modifying flowering time in a plant comprising transforming a plant with a nucleic acid encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2.

Claim 8 is not specifically directed to a method wherein a plant is transformed with a nucleic acid encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2, but to transforming a plant to alter expression of a peptide having either the amino acid sequence of SEQ ID NO: 2 [sic]. Since Applicant has failed to teach all

methods of altering expression of said peptide, Applicant has failed to fully enable the claimed method and it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to transform a plant with a myriad of undisclosed nucleic acid to determine those nucleic acids that alter expression of a polypeptide having the amino acid sequence of SEQ ID NO: 2.

Claims 4 and 6 are directed to expressing or overexpressing a polypeptide consisting of an amino acid sequence having at least 80% identity to SEQ ID NO: 2. The art teaches that one of skill in the art cannot predictably identify other CK2 α-subunit homologs of the same plant species even using a full-length cDNA probe (Lee *et al* 1999, Plant Physiology 119:989-1000, see page 993, Figure 4). Hence, because Applicant has failed to teach other CK2 β-subunit genes and/or how to identify and isolate other such genes it would have required one of skill in the art at the time of Applicant's invention undue trial and error experimentation to isolate all genes encoding an amino acid sequence having at least 80% identity to the amino acid sequence shown in SEQ ID NO: 2, transform a host cell or a plant and identify those transgenic plant htat also have altered flowering time.

At claim 5, Applicant claims a transgenic plant overexpressing a nucleic acid complementary to SEQ ID NO: 1, but Applicant fails to teach one of skill in the art how to use such a plant other than *Arabidopsis thaliana*. Applicant's arguments do not specifically address the issues as directed to the rejection of claim 5 as not enabled for any plant expressing an antisense construct to SEQ ID NO: 1 (page 5 of the Remarks). The art teaches that overexpressing an antisense nucleic acid encoding an *Arabidopsis*

thaliana CK2 α-subunit gene had no effect in inhibiting expression of a gene that is 97% identical (Lee *et al* 1999, Plant Physiology 119:989-1000, see page 993). Hence, it would have required undue trial and error experimentation for one of skill in the art at the time of Applicant's invention to successfully inhibit endogenous gene expression in any plant with an antisense nucleic acid of SEQ ID NO: 1.

At claim 9, Applicant has only taught a method of altering circadian rhythms and flowering in a plant comprising overexpressing a nucleic acid encoding a polypeptide having the amino acid sequence of SEQ ID NO: 2. Given the breadth of the claimed method of changing activity of protein kinase CK2 within a plant it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's inventions to change activity of protein kinase CK2 within a plant utilizing all mechanisms as broadly claimed.

Claim Rejections - 35 USC § 102

11. Claim 9 remains rejected under 35 U.S.C. § 102(b) as being anticipated by Carter *et al* 1991 (The EMBO Journal 10(8): 2063-2068). This rejection is repeated for the reasons set forth in the previous Office action mailed 26 September 2001. Applicant's arguments filed 13 February 2002 have been fully considered but they are not persuasive.

Applicant argues that there is no showing that PEPc kinase is CK2 and that to anticipate a claim each and every element must be met (page 7 of the Remarks). This argument is not found to be persuasive because the method of Carter *et al* teaches all of the required method steps required to practice the claimed method. The method of

Carter *et al* would inherently change activity of protein kinase CK2 within a plant. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (holding that a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia* is anticipated by a method of inoculating a plant with the same bacterium in order to protect a plant from fungal disease). (see also *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846 at 1851 (DC SCalif 1999)).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 4 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Collinge *et al* 1994 (Plant Molecular Biology 25:649-658). This rejection is made in view of Applicant's amendments to the claims in the response filed 13 February 2002. Applicant's arguments are addressed below.

Collinge teaches a *Saccharomyces cerevisiae* host cell expressing a heterologous peptide, said peptide is a *Arabidopsis thaliana* casein kinase II β subunit which is 70% identical to Applicant's SEQ. I.D. No. 2. Collinge teaches both a CKB1 and a CKB2 genes and polypeptides, said polypeptides are 80% identical to each other (see Fig. 3 on page 653). Collinge teaches a method of isolating CK2 (syn. casein kinase II) β-subunits by complementing a conditional mutation in *Saccharomyces cerevisiae* (see page 651). The method of isolating taught by Collinge is the same used

by Applicant in identifying the exemplified CKB3 gene and polypeptide (see pages 9-10 of the specification).

Collinge does not teach a polypeptide having at least 80% sequence identity to that of SEQ ID NO: 2, or a transgenic plant overexpressing such a polypeptide.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to follow the teachings of Collinge to identify a gene encoding a polypeptide having at least 80% sequence identity to that of Applicant's SEQ ID NO: 2, especially from *Arabidopsis thaliana*. Collinge teaches that the CKB1 and CKB2 are 80% identical to each other (see 3rd paragraph of the Abstract on page 649). Collinge teaches that the subunit composition and properties of the holoenzyme may vary in different tissues or conditions (see page 656, right column, 3rd paragraph). Although Collinge does not specifically teach a polypeptide having at least 80% sequence identity to that of SEQ ID NO: 2, one of ordinary skill in the art at the time of Applicant's invention would have had a reasonable expectation of success in identifying such a polypeptide that lies within the claimed subgenus of CK2 β-subunit polypeptides given the teachings of Collinge. Collinge also teaches that in plants casein kinase II has been shown to regulate transcription factor binding activities by phosphorylation, hence one of ordinary skill in the art at the time of Applicant's invention would have been motivated to produce transgenic plants overexpressing such a polypeptide (see paragraph spanning the columns on page 650).

Conclusion

14. This action is non-final

15. Claims 1, 2, 5, 7 and 8 are free of the prior art which neither teaches nor fairly suggests the nucleic acid sequence of SEQ ID NO: 1 or the amino acid sequence of SEQ ID NO: 2 and method of using same.

16. Claims 1 and 2 are allowed, claim 7 is objected to.

17. Claims 4-6, 8 and 9 remain rejected.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

AMY J. NELSON, PH.D
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David H. Kruse, Ph.D.
24 March 2003